



IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant: Mason

Atty Dkt: 2731/101

Serial No: 09/976,685

Art Unit: 3732

Date Filed: October 11, 2001


Examiner: D. A. Bonderer

Invention: Graftless Spinal Fusion Device

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**CERTIFICATE OF MAILING**

I hereby certify that this correspondence is being deposited with the United States Postal Service as first class mail in an envelope addressed to Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450 on May 29, 2003.

  
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John L. Conway

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Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

**DECLARATION IN SUPPORT OF APPLICANT'S RESPONSE**  
**[37 C.F.R. Section 1.132]**

The undersigned Michael Mason does hereby declare as follows:

1. My name is Michael Mason and I am the inventor of the invention disclosed in the above-referenced application. I have been awarded the following degrees: Doctor of Osteopathic Medicine, Philadelphia College of Osteopathic Medicine, 1987; Bachelor of Science, Chemistry and Biology, West Chester University, 1983, *magna cum laude*. I am a licensed medical doctor in the Commonwealths of Massachusetts and Pennsylvania. I am board certified in Orthopedic Surgery and have practiced in this field for over 10 years. I have also

designed four orthopedic devices. These devices are currently approved and manufactured worldwide. I consider myself skilled in the art of orthopedic device design. The attached curriculum vitae provides further details on my background.

2. I have reviewed the office action mailed on December 31, 2002 and the cited references: Hirayama et al., "Artificial Intervertebral Disc," U.S. Pat. ser. no. 4,946,378 and Ferree, "Artificial Intervertebral Disc Replacement Methods and Apparatus," U.S. Pat. ser. no. 6,419,704.

3. Hirayama's implant is a replacement for a disc. The implant separates and cushions the adjacent vertebrae. This implant is meant to maintain motion between these vertebrae. In contrast, my implant is for spinal fusion which eliminates relative motion of adjacent vertebrae. Hirayama's implant cannot be used for spinal fusion since it lacks the required rigidity.

4. Ferree teaches an artificial replacement for intervertebral discs. This replacement makes use of a shaped body having a final volume sized to consume at least a portion of an intervertebral disc space, and a filling within the shaped body enabling the body to cyclically compress and expand in a manner similar to the disc material being replaced. The filling may be a gas, liquid or a gel. Like the Hirayama device, the Ferree device is unsuitable for fusing vertebrae since the device does not provide the rigidity required, i.e., the device does not provide the response to sheer or tensile stress needed to immobilize the vertebrae.

5. The implant devices I invented are superior to prior art intervertebral fusion devices that require a bone graft. Embodiments of my invention include members protruding from an implant body. The members and associated body surfaces may be coated with a bioactive coating. This bioactive coating allows these members to rapidly attach to keyways formed in the corresponding vertebrae. The relatively rigid materials that may comprise the implant body (such as titanium steel in one version) effectively immobilize the adjacent vertebrae after insertion, achieving fusion without the use of a bone graft.

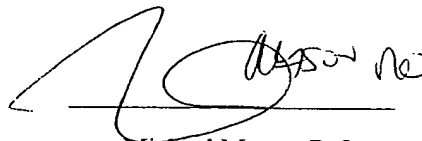
6. In inventing implants and the associated methods for spinal fusion, I realized that the shape and placement of the protruding members of the implant were important for enhancing bonding of the implant to the vertebrae. First, an empirical formula for what I call "fixation" of the member into the vertebra was developed. Fixation is the degree to which the protruding member bonds to the vertebral bone. The greater the fixation, the more stress the bond can take. The extent of fixation is equal to the surface area of the member times the density of the bone to which the member is bonded. For example, a horseshoe-shaped protruding member, with its convex profile, provides more surface area than a dovetail-shaped member and should provide better bone fixation.

7. Secondly, cortical bone, which is at the periphery of a bone, is denser than bone at the center of a bone and embodiments of the present invention take advantage of this configuration. In one embodiment of my

invention, we provide two members on an implant surface, positioned away from the center of the surface, so that each of the members is anchored in the denser bone near the outside of a vertebra. This placement of members enhances fixation.

8. Thirdly, since bone formation will increase in areas subjected to compression according to Wolff's Law, a horseshoe-shaped protruding member should facilitate growth of denser bone near points where the protruding member meets the body of the implant. This follows since bone in this area is subjected to a higher level of compression than is the case for a dove-tail shaped member: the dovetail "shadows" the developing bone in this area from compressive stresses that are passed along for the horseshoe-shaped protruding member. Thus, fixation of the implant in the vertebrae is further enhanced. The effect of the shape of a protruding member on vertebral fixation for the implant, when inserted, is not obvious. It is not a simple matter of design choice.

9. I further state that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements are made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issuing thereon.



Michael Mason, D.O.

248720.2



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### EDUCATION

**COLLEGE:**

West Chester University, 1983  
Bachelor of Science, Chemistry and Biology  
Magna Cum Laude

**MEDICAL SCHOOL:**

Philadelphia College of Osteopathic Medicine  
Doctor of Osteopathic Medicine, 1987

### TRAINING

**INTERNSHIP:**

7/87 - 6/88

Rotating Internship  
Community General Hospital  
Harrisburg, PA

**RESIDENCY:**

7/88 - 6/92

Orthopaedic Surgery  
Community General Hospital  
Harrisburg, PA

Visiting Resident

Harvard Combined Orthopaedic Residency Program  
Boston, MA

**FELLOWSHIP:**

8/92 - 7/93

Adult Reconstruction  
Harvard Medical School  
Brigham & Women's Hospital  
Boston, MA

### CERTIFICATION and LICENSURE

**BOARD CERTIFIED:**

American Osteopathic Board of Orthopedic Surgeons, 1996

**DIPLOMATE:**

National Board of Medical Examiners, 1988

**MEDICAL LICENSURE:**

Massachusetts, (80434)  
Pennsylvania, (OS 006572L)

### MILITARY SERVICE

**UNITED STATES ARMY:**

Presidential White House Honor Guard, 1975, 1976  
Washington, D.C.

**ACADEMIC APPOINTMENTS**

**Boston University  
School of Medicine:**  
Boston, MA

Assistant Professor in Orthopaedic Surgery  
April 1994 - Present

**Harvard Medical School:**  
Boston, MA

Clinical Instructor In Orthopaedic Surgery  
August 1993 - Present

**Harvard Medical School:**  
Boston, MA

Clinical Fellow In Orthopaedic Adult Reconstruction  
August 1992 - July 1993

**PROFESSIONAL EXPERIENCE**

**Boston University  
School of Medicine:**  
Boston, MA

Assistant Professor in Orthopaedic Surgery, 4/94 - Present  
University Hospital  
Boston City Hospital

**Howmedica Osteonics:**  
Allendale, NJ

Consultant, 1994 - Present

**Harvard Medical School:**  
Boston, MA

Clinical Instructor In Orthopaedic Surgery, 8/93 - 3/94  
Massachusetts General Orthopedic Associates  
The Cambridge Hospital

**Harvard Medical School:**  
Boston, MA

Clinical Fellow In Orthopaedic Adult Reconstruction, 8/92 - 7/93  
Brigham and Women's Hospital

**Community General  
Hospital:**

Chief Surgical Resident, 7/91 - 6/92

**PROFESSIONAL ORGANIZATIONS**

American Osteopathic Academy of Orthopaedic Surgeons

American College of Osteopathic Surgeons

Massachusetts Medical Society

Massachusetts Osteopathic Society  
Treasurer, Board of Directors

American Osteopathic Association

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**PUBLICATIONS**

*Total Elbow System Surgical Protocol*

Inglis AE, Bonutti PM, Rosenberg G, Coleman DA, Mason MD  
Solar Upper Extremity System  
Stryker Howmedica Osteonics

*Total Shoulder System Surgical Protocol*

RH Bell, Bonutti PM, Morris HB, Mason MD, Naylor P, Rosenberg G  
Solar Upper Extremity System  
Stryker Howmedica Osteonics

*Total Elbow System Surgical Protocol*

Ford M, Hall H, Mason MD, Nash C, Stephens C, Vaughan JJ, Armstrong D, Lapresle P, Missenard G  
Osteonics Spinal System  
Posterior System Surgical Protocol  
Osteonics Corporation

*The Effect of Component Design on the Performance of Glenoid Prostheses*

Orr TE, Wong, BE, Mason, MD  
Journal of Shoulder and Elbow Surgery  
In Press

*Kinematic Total Knee Arthroplasty: A Ten to Fourteen Year Prospective Follow-Up Review*

Ewald FC, Wright RJ, Poss R, Thomas WH, Mason MD and Sledge CB  
Journal of Arthroplasty  
June 1999

*Assessment of Neuroforaminal Decompression in Degenerative Spinal Stenosis*

Gill TJ, Mason MD  
Clinical Orthopaedics and Related Research  
March 1998

*Techniques to Reduce Susceptibility Artifact*

Eustace S, Yucel EK, Melhem, Mason M, Goldberg Right  
American Journal of Radiology  
February 1998

*A Comparison of Conventional Spine-Echo and Turbo Spin Echo Sequences in the Imaging of Orthopaedic Hardware*

Eustace S, Jara H, Goldberg R, Fenlon H, Mason M, Melhen ER, Yucel EK  
American Journal of Radiology  
February 1998



*Rice Body Formation in Bicipito-Radial Bursitis: Ultrasound, CT and MRI Findings*

Spence LD, Adams J, Gibbons D, Mason MD and Eustace S

Skeletal Radiology

January 1998

*Current Imaging of Orthopaedic Hardware*

Eustace S, Mason MD

Orthopaedic Clinics of North America

January 1998

*Imaging Orthopedic Hardware with an Emphasis on Hip Prostheses.*

Eustace S, Shah B, Mason M

Orthopedic Clinics of North America

January 1998

*Ten to Fourteen Year Review of a Non-Constrained Cruciate Retaining Condylar Total Knee Arthroplasty*

Orthopaedic Transactions

J Bone and Joint Surgery

Vol 17,(4),1091, 1993

*Three Pegged All Polyethylene Resurfacing Patellae: Two to Six Year Results*

Mason MD, Brick GW, Scott RD and Ewald FE

Orthopaedic Transactions

J Bone and Joint Surgery

Vol 17,(4),1091, 1993

*Chronic Complicated Osteomyelitis of the Lower Extremity: Evaluation With MR Imaging*

Mason MD, Zlatkin MJ, Esterhai JL, Dalinka MK and Kressel HY

Radiology 1989; 173: 355 - 359

*The Formation of the Gray Crescent in the Unactivated Egg of Rana pipiens*

Zimmerman ID and Mason MD

American Zoologist 1983; 23: 4

**PRESENTATIONS**

*Quantification of Pedicle Screw Toggle Movements During Cyclic Bending Loads: Conical vs. Cylindrical Pedicle Screws*

Jensen L, Szirtes B, Mason M, Nolte L, Orr The

Orthopedic Research Society

Poster Exhibit

Orlando, 2000

*Factors Affecting Prosthetic Design in TSR and Complications of TS: Recognition and Treatment*

State of the Art in Orthopaedics 2000

Whistler, British Columbia, 2000

*The Effect of Implant Design on the Stability of Glenoid Components*  
American Academy of Orthopaedic Surgeons 64<sup>th</sup> Annual Meeting  
Poster Exhibit  
San Francisco, 1997

*The Effect of Component Fixation Design on the Performance of Glenoid Prostheses*  
Orr TE, Wong BE, Maw K, Ashmore WP, Mason MD  
Orthopaedic Research Society 43<sup>rd</sup> Annual Meeting  
San Francisco, 1997

*MR Imaging of Orthopaedic Hardware: Techniques to Reduce Susceptibility Artifact*  
Goldberg R, Jara H, Mason MD, Yucel EK, Eustace S  
Radiological Society of North America  
Chicago, 1996

*The Elbow: The Forgotten Joint*  
American Osteopathic Academy of Orthopaedics Annual Meeting  
Dearborn, 1996

*The Space Available for the Nerve Root in the Senescent Lumbar Spine*  
Mason MD, Gill T  
American Academy of Orthopaedic Surgeons 63<sup>rd</sup> Annual Meeting  
Poster Exhibit  
1996

*MR Imaging of Orthopaedic Hardware: Techniques to Reduce Susceptibility Artifact*  
Goldberg R, Jara H, Mason MD, Yucel EK, Eustace S  
American Radiology Society  
San Diego, 1995

*Intra-operative Assessment of Neuroforaminal Decompression in Spinal Stenosis Surgery*  
Mason MD, and Gill TE  
Scientific Program Presentation  
American-European Meeting on Pedicle Fixation of The Spine and Other  
Advanced Techniques  
Munich, Germany  
July, 1994

*Examination of Regional Bone Densities Within the Glenoid Vault: Influence on Component Design and Stability*  
Mason MD, Kalus RM, Thornhill TS and Cheal EJ  
Scientific Program Presentation  
Orthopaedic Research Society  
New Orleans, Louisiana  
February, 1994

*Ten to Fourteen Year Review of a Non-Constrained Cruciate Retaining Condylar Total Knee Arthroplasty*  
Mason MD, Ewald FE, Sledge CB and Wright JR  
Scientific Program Presentation  
American Academy of Orthopaedic Surgeons  
San Francisco, 1993

*Three Pegged All Polyethylene Resurfacing Patellae: Two to Six Year Results*

Mason MD, Brick GW, Scott Rd and Ewald FE

Scientific Program Presentation

American Academy of Orthopaedic Surgeons

San Francisco, 1993

*Proximal Femoral Allografts in Revision Total Hip Arthroplasty; Surgical Technique and Results*

Mason MD, Vaneenaman P and Brick EW

Scientific Program Presentation

Pennsylvania Orthopaedic Society

Bermuda, 1993

*Evaluation of Chronic Complicated Osteomyelitis: A Comparison of MRI and Indium-111 Scanning*

Mason MD and Zlatkin MJ

Scientific Program Presentation

Roentgenological Society of North America

Chicago, 1988